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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/579,469 12/27/95 AKAZAWA

M	
EXAMINER	
PHELAN, D	
ART UNIT	PAPER NUMBER

15M1/0520

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1502
DATE MAILED:

05/20/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

- ☒ Claims 5-8 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☒ Claims 1-4 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 5-8 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed, additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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Part III DETAILED ACTION

Acknowledgement is made of the Preliminary amendment filed December 27, 1995. Claims 1-4 are cancelled. New claims 5-8 are pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

2. Claims 5, 6 and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Assandri et al (Drugs Exptl. Clin Res.).

Assandri discloses a pharmaceutical plaster comprising diclofenac hydroxyethylpyrrolidine and a variety of excipients for topical pharmaceutical use. Assandri does not disclose that the pH of the preparation is adjusted to a range of 7.3 to 9.0.

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However it is the position of the examiner that, given "a variety of excipients", the ph of the plaster of Assandri may be within applicant's lacking any evidence to the contrary.

3. Claim 8 is rejected under 35 U.S.C. § 103 as being unpatentable over Assandri as applied to claims 5,6 and 9 above, and further in view of Okuyama (EPO 0,524,582).

Assandri discloses a diclofenac hydroxyethylpyrrolidine plaster substantially as described above. Not disclosed is the method of making the plaster. Okuyama is relied upon for teaching the process of making a diclofenac sodium plaster (col 4, l 36-57). It is the position of the examiner that one of ordinary skill in the art would use the process of making of Okuyama to prepare the plaster of Assandri, since Okuyama has shown that a plaster of a diclofenac salt can be successfully made by mixing diclofenac salt with excipients such as sodium carboxymethylcellulose, gelatin, tartaric acid etc., dispersing some of the ingredients in water, kneading the mixture into a paste and spreading on a support (col 4, l 36-57).

In comments accompanying the amendment, Applicant urges that one of the unexpected effects of the present invention is "that the pharmaceutical effect is kept for a long period of time ... because the pH adjuster maintains the desirable pH value for suitably controlling release of the salt." Applicant then indicates that an attached graph shows "that the effect is kept

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for a long time". The examiner notes that such a graph is not part of the original, sworn to, declaration. Further, the graph doesn't indicate that it is the diclofenac hydroxyethyl pyrrolidine salt which is being used or at what pH the plaster or gel is maintained. Applicants additional comments directed to crosslinking agents are of little value, since, as indicated by applicant, the crosslinking agents are optional.

Conclusion

4. This is a Continuation of applicant's earlier application S.N. 08/226,875. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE

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MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Gabrielle Phelan, Ph.D. whose telephone number is (703) 308-0756.

The Examiner can normally be reached on Monday through Thursday from 7:00 AM to 4:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at 703-308-2927. The fax phone number for this Art Unit is 703-305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703-308-2351.

dgp
May 16, 1996


J. GABRIELLE PHELAN, PhD
PRIMARY EXAMINER
GROUP 1500